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| APPLICATION NO.                                     | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO |
|---|----------------|----------------------|---------------------------------|-----------------|
| 09/963,698  | 09/26/2001     | Francis Barany       | 19603/3355 (CRF<br>D-1595E)     | 2018            |
| 75  | 590 09/08/2003 |                      |                                 |                 |
| Michael L. Goldman NIXON PEABODY LLP Clinton Square |                |                      | EXAMINER                        |                 |
|   |                |                      | PONNALURI, PADMASHRI            |                 |
| P.O. Box 31051<br>Rochester, NY 14603               |                |                      | ART UNIT                        | PAPER NUMBER    |
| ,   |                |                      | 1639<br>DATE MAILED: 09/08/2003 | 10              |

Please find below and/or attached an Office communication concerning this application or proceeding.

| • ,   |  | Application No.   | Applicant(s)  |
|---|--|---|---|
|   |  | 09/963,698  | BARANY ET AL.   |
| 1   | Office Action Summary  | Examiner  | Art Unit  |
|   |  | Padmashri Ponnaluri   | 1639  |
| Period fo   | The MAILING DATE of this communication a   | ppears on the cover sheet with the  | correspondence address  |
| THE N - Extending after S - If the - If NO - Failure - Any re | ORTENED STATUTORY PERIOD FOR REF MAILING DATE OF THIS COMMUNICATION asions of time may be available under the provisions of 37 CFR SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reperiod for reply is specified above, the maximum statutory period to reply within the set or extended period for reply will, by state eply received by the Office later than three months after the main adparent term adjustment. See 37 CFR 1.704(b). | I.  1.136(a). In no event, however, may a reply be ti eply within the statutory minimum of thirty (30) da od will apply and will expire SIX (6) MONTHS from ute, cause the application to become ABANDONI | mely filed  ys will be considered timely.  n the mailing date of this communication.  ED (35 U.S.C. § 133). |
| 1)⊠   | Responsive to communication(s) filed on 24   | 4 June 2003 .   | •   |
| 2a) <u></u> □   | This action is <b>FINAL</b> . 2b)⊠   | This action is non-final.   |   |
| 3)□<br>Dispositi  | Since this application is in condition for allo closed in accordance with the practice unde on of Claims   |   |   |
| 4) 🖂  | Claim(s) 89-119 is/are pending in the applic   | ation.  |   |
| •   | 4a) Of the above claim(s) <u>98-108 and 113-11</u>   | 19 is/are withdrawn from considera  | tion.   |
| 5) 🗌  | Claim(s) is/are allowed.   |   |   |
| 6)⊠   | Claim(s) 89-97,109,111 and 112 is/are reject   | ted.  |   |
| 7) 🗌  | Claim(s) is/are objected to.   |   |   |
|   | Claim(s) are subject to restriction and on Papers  | or election requirement.  |   |
| 9) 🔲 🗆  | The specification is objected to by the Exami  | ner.  | •   |
|   | The drawing(s) filed on is/are: a)☐ acc  |   | aminer.   |
|   | Applicant may not request that any objection to  |   |   |
| 11) 🔲 🗆   | The proposed drawing correction filed on   | is: a)□ approved b)□ disappr  | oved by the Examiner.   |
|   | If approved, corrected drawings are required in  | reply to this Office action.  |   |
| 12)🛛 🖯  | The oath or declaration is objected to by the l  | Examiner.   |   |
| Priority u  | ınder 35 U.S.C. §§ 119 and 120   |   | 4   |
| 13)   | Acknowledgment is made of a claim for forei  | gn priority under 35 U.S.C. § 119(  | a)-(d) or (f).  |
| a)[   | ☐ All b)☐ Some * c)☐ None of:  |   |   |
|   | 1. Certified copies of the priority docume   | nts have been received.   |   |
|   | 2. Certified copies of the priority docume   | nts have been received in Applicat  | tion No   |
|   | 3. Copies of the certified copies of the prapplication from the International Bee the attached detailed Office action for a li   | Bureau (PCT Rule 17.2(a)).  | _   |
|   | cknowledgment is made of a claim for dome  |   |   |
| a)  | )  The translation of the foreign language packnowledgment is made of a claim for dome   | provisional application has been re   | ceived.   |
| م الحصارات ا<br>Attachment                                    |  | The priority dilater to the co. 33 12   | - ana, 01 (£1.  |
| 1) 🔀 Notice<br>2) 🔲 Notice                                    | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)  | 5) Notice of Informal   | ry (PTO-413) Paper No(s) Patent Application (PTO-152)   |
| S. Patent and Tr<br>TOL-326 (Re                               |  | Action Summary  | Part of Paper No. 10  |

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#### **DETAILED ACTION**

- Applicant's election of Group I, claims 89-112, and glass as species for solid support, different nucleic acids as species of capture oligonucleotides, carboxyl groups as species to functionalize the solid support, acrylic acid as the species of monomer used in polymerization, O-nitrobenzyloxycarbonyl as species of photoactivatable group, and a barrier oligonucleotides shorter than the capture probes; in Paper No. 9, filed on 6/24/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Applicants along with the election noted that 'all the groups of the invention identified in the office action are closely related and therefore, would require common areas of search and consideration. Applicants arguments have been considered and are not persuasive because group I and group II inventions even though closely related the methods are patentably distinct from each other and the search for group I would not result in finding references for group II (i.e., the references used for group I claim rejections would not be obvious over group II claims). Thus the restriction has been maintained.
- 3. Claims 113-119 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.
- 4. Claims 98-108 (dependent on claim 99) 110 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

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5. Claims 89-119 are pending in this application and Claims 89-97, 109, 111-112 are currently being examined in this application.

### **Drawings**

6. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

#### Oath/Declaration

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

NOTE that the citizenship, and address of inventor 'Maria Kempe' have been changed withour initials.

# Claim Rejections - 35 USC § 112

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 9. Claims 89-97, 109, 111-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 89 recites the limitation "the array of a plurality of capture oligonucleotides" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 89 recites the limitation "the activated array positions" in line 9. There is insufficient antecedent basis for this limitation in the claim.

## Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 89-97, 109 and 111-112 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,510,270 (Fodor et al).

The instant claims briefly recite a method of forming arrays of oligonucleotides on a solid support by attaching to the solid support a linker suitable for coupling oligonucleotides, and forming an array of a plurality of capture oligonucleotides by series of cycles of activating selected array positions for attachment of multimer nucleotides.

Fodor et al teach a method for synthesizing and screening oligonucleotides on a solid support. The method provides for the irradiation of a first predefined region of a substrate comprising immobilized nucleotides on its surface, without irradiation of a second predefined region of the substrate. The irradiation step removes a protecting group from the immobilized nucleotides. The substrate is contacted with a first nucleotide to couple the nucleotide to the

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immobilized nucleotides in the first predefined region without coupling in the second predefined region. At least a part of the first predefined region and at least a part of the second predefined region are subjected to further irradiation. The substrate is contacted with a second nucleotide, which couples to the immobilized nucleotides in at least part of the first and at least part of the second predefined regions. By repeating these steps, an array of diverse oligonucleotides is formed on the substrate (refers to the instant claimed method) (i.e., see abstract). Fodor et al teach the solid support is substantially flat and may have wells, raised regions, etched trenches, or the like (i.e., see column 7, under substrate or in column 11) (refers to instant claims 94). Fodor et al teach that the substrate surface is composed of inorganicglass (i.e., see column 11) (refers to instant claims 91-92). Fodor et al teach that the substrate is conventional microscope slide or coverslip (i.e., see column 16) (refers to instant claim 92). Fodor et al teach the use of 'nitrobenzyloxy carbonyl' as the protecting group (i.e., see column 7) (refers to instant claim 106). Fodor et al teach that the surface of the substrate contains reactive groups which can be carboxyl, amino, hydroxyl (refers to instant claim 97)(i.e., see column 11). Fodor et al teach that the any conceivable substrate may be employed in the invention. The substrate may be in the form a sheet, tubing spheres, plates, films, and the any convenient shape such as disc, square, sphere, circular, and the substrate may contain raised or depressed regions on which the synthesis takes place (refers to instant claim 95) (i.e., see column 11). Fodor et al teach that the substrate is polymerized with gels or polymers such as (poly)tetrafluoroethylene, (poly)vinylidenedifluoride, polystyrene, polycarbonate (refers to instant claim 104 )(i.e., see column 11).

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Fodor et al use a mask to illuminate( or irradiate) selected regions of the substrate and uses photolithographic technique in synthesis of polymer arrays. Fodor et al teach that a square area is divided into square boxes, and the first reactions are carried out in the vertical columns and the process is repeated in the horizontal direction for the second unit of dimmer (i.e., see columns 18-19) (refers to instant claim 90). Fodor et al teach that one mask can be used in al eight steps if it is suitably rotated and translated. For example, a mask with as ingle transparent region could be sequentially used to expose each of the vertical columns, translated 90 of and then sequentially used to allow exposure of the horizontal rows. Fodor et al teach that by controlling the locations of the substrate exposed to light and the reagents exposed to the substrate following exposure the locations of each sequence will be known (i.e., see column 9). The Thus the reference clearly anticipates the claimed invention.

12. Claims 89-94, 96-97, 109, 111-112 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,527,681 (HOLMES).

Holmes et al teach a synthetic strategy for the creation of large scale chemical diversity using solid phase chemistry, photo labile protecting groups and photolithography achieve light directed spatially addressable parallel chemical synthesis of an array of polymers (i.e., see abstract). Holmes teaches that the preferred embodiment provides for the synthesis of an array of polymers in which individual monomers in a lead polymer are systematically substituted with monomers from one or more basis sets of monomers. The reference teaches that the substrate is flat and it may have synthesis regions separated by structures, and the surface may have wells, raised regions, or etched trenches (i.e., see column 5). The reference teaches that the substrate has linker molecules which are optionally protected with photo removable protecting groups.

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The reference teaches that the mask is used and rotated for the following coupling steps. The reference claims and specification disclosure are drawn to a method of synthesizing an array of oligonucleotides on a surface of a substrate clearly anticipates the claimed invention.

13. Claims 89, 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipshutz et al (BioTechniques, Vol 19, No. 3, 1995, pages 442-447).

Lipshutz et al teach high density oligonucleotide arrays created using light directed chemical synthesis. Light-directed chemical synthesis combines semiconductor based photolithography and solid phase chemical synthesis. The reference teaches linkers modified with photochemically removable protecting groups are attached to a solid substrate. Light is directed through a photolithographic mask to specific areas of the synthesis surface, activating those areas for chemical coupling. The first of a series of nucleoside harboring a photolabile protecting group at the 5'end is incubated with the array, and chemical coupling occurs at those sites that have been illuminated in the preceding step, next light is directed to a different region of the substrate through a new mask, and the chemical cycle is repeated. Using the proper sequence of masks and chemical steps, a defined collection of oligonucleotides can be constructed, each in a predefined position on the surface of the array. The reference clearly anticipates the claimed invention.

14. Claims 89 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al (Nature, vol. 364, August 1993, pages 555-556).

Fodor et al teach a method of preparing miniature biological arrays using light directed combinatorial chemical synthesis of biopolymers on a solid support. Fodor et al teach light directed chemical synthesis employs semiconductor based photolithography and solid phase

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14. Claims 89 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Fodor et al (Nature, vol. 364, August 1993, pages 555-556).

Fodor et al teach a method of preparing miniature biological arrays using light directed combinatorial chemical synthesis of biopolymers on a solid support. Fodor et al teach light directed chemical synthesis employs semiconductor based photolithography and solid phase chemical synthesis. Synthesis linkers modified with photo chemically removable protecting groups are attached to a solid support, light is directed through a photolithographic mask to specific areas of the synthesis surface effecting localized photodeprotection. The first of series of chemical building blocks is incubated with the surface and chemical coupling occurs at those sites which have been illuminated in the preceding step. Next the light is directed to a different region of the substrate through a new mask, and the chemical cycle is repeated. The reference clearly anticipates the claimed invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached on Monday through Friday between 7.30 AM and 3.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri Primary Examiner Art Unit 1639

Pp

5 September 2003

PADMASHRI PONNALURI PRIMARY EXAMINER